

polynucleotides of SEQ ID NOS:1-12 as normal urinary tract tissue is the host tissue of these polynucleotides. The polynucleotides are of interest when they are overexpressed in a tissue or body compartment where their normal occurrence is very low or non-existent. Such overexpression indicates that a disease has altered the polynucleotides so that they escape from their host tissue (in this case urinary tract tissue) into other areas of the body. Thus, these polynucleotides are useful as markers for the detection of disease

in urinary tract tissue. Applicant has previously submitted several Exhibits, which describe such a diagnostic technique used with prostate specific antigen (PSA) and carcinoembryonic antigen (CEA). Further, Applicant has cited several references in the specification (for example, at p. 3, lines 4-7), which show that this detection technique is one that is well-known in the art. Therefore undue experimentation would not be necessary to use well-known techniques for the detection of disease with the polynucleotides of the instant invention in order to detect urinary tract disease.

Therefore, Applicant asserts that the examples and methods disclosed in the specification are enabling for, at the least, urinary tract diseases that may be detected using gene markers and related gene marker technology as are well known in the cancer diagnostic art. Nevertheless, in an effort to clarify, Applicant submits new claims 22-54 which include the term "urinary tract cancer" in addition to "urinary tract disease". Both these terms are supported in the specification at page 18, lines 26-34. Applicant respectfully submits that the new claims are now in a condition for allowance and requests that this rejection be withdrawn.

Claims 1-9 are rejected under 35 USC 112, first paragraph. The Examiner states that the specification does not reasonably provide enablement for polynucleotides having 70% identity to SEQ ID NOS:1-12. These claims have been cancelled.

Some of new claims 22-54 also include percent identity language. The Examiner also states that the specification does not provide adequate instruction of how to use the broadly claimed polynucleotides having at least 70% identity with a reasonable expectation of success. Applicant disagrees. However, in an effort to clarify, Applicant has added "isolated" and "purified" language to the claims. Furthermore, in an effort to

expedite prosecution, Applicant has raised the percent identity to 95% and included language to clarify that identity is "over the entire length" of the claimed SEQ ID NO.

The Examiner states that the specification is enabling for polynucleotides have 100% identity to SEQ ID NOS:1-12 and complements thereof. New claims 31-42 incorporate this language.

New claims 43-54 are further clarified by "degenerate codon equivalents" language. The degeneracy of the genetic code is a concept that is well-known to those skilled in the art and is even discussed in section 2144.09 of the February 2000 revision of the Manual for Patent Examining Procedure as "the fact that most amino acids are specified by more than one nucleotide sequence or codon." Applicant respectfully submits that the new claims are in a condition for allowance and requests that this rejection be withdrawn.

Claim 1 is rejected under 35 USC 103(a) as being unpatentable over any of Accession numbers AA389615, N32615, N32011, H02338 or H96372 in light of Maniatis. This rejection is respectfully traversed.

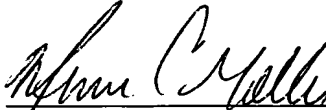
Claim 1 has been cancelled. New independent claim 22 is directed to sequences with at least 95% identity over the entire length of a sequence selected from the group consisting of SEQ ID NO:1, SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:8, and SEQ ID NO:10. New independent claim 31 is directed to SEQ ID NOS:1-12 and complements thereof. New independent claim 43 is directed to SEQ ID NOS:1-12 and degenerate codon equivalents thereof. Applicant respectfully submits that the new claims are in a condition for allowance and requests that this rejection be withdrawn.

### **CONCLUSION**

In view of the aforementioned amendments and remarks, Applicant respectfully submits that the above-referenced application is now in a condition for allowance and

Applicant respectfully requests that the Examiner withdraw all outstanding objections and rejections and passes the application to allowance.

Respectfully submitted,  
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